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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/762,223	05/07/2001	Antony Walter Anson	78014.018	2854

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EXAMINER

MILANO, MICHAEL J

ART UNIT PAPER NUMBER

3731

DATE MAILED: 02/19/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/762,223

Applicant(s)

ANSON ET AL.

Examiner

Paul A Roberts

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 December 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 51-70 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 51-61 and 63-70 is/are rejected.
- 7) ☒ Claim(s) 62 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 12.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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DETAILED ACTION

Priority

1. Acknowledgment is made of applicant's claim for foreign priority based on two applications filed in GB and on 08/03/98. It is noted, however, that applicant has not filed a certified copy of the GB patent application as required by 35 U.S.C. 119(b).
2. This application filed under former 37 CFR 1.62 lacks the necessary reference to the prior application. A statement reading "This is a continuation of Application No. 05/07/2001, filed 08/03/1998." should be entered following the title of the invention or as the first sentence of the specification. Also, the current status of the parent nonprovisional application(s) should be included.

Drawings

3. The corrected or substitute drawings were received on 12/31/02. These drawings are accepted by the examiner.

Specification

4. Corrections to the specification were received on 12/30/02. The corrections are accepted by the examiner.
5. Addition of the abstract was received on 12/30/02. The abstract is accepted by the examiner.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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6. Claims 51-63 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The resilient member does **not** bias the first and second parts. Though the specification provides enablement and disclosure for this feature, both the specification and claim 51 incorrectly attribute the bending motion of the staple to the resilient member. The biasing force that changes the shape of the first and second parts is the stored, mechanical, spring-type energy in the first and second parts, not the resilient member.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 51, 53-61, 63-64, and 66-70 are rejected under 35 U.S.C. 102(b) as being anticipated by Krumme, US 4,485,816.

7. Regarding claims 51 and 58, Krumme discloses a surgical staple containing a plurality of first and second parts connected by a resilient member wherein the first and second parts become close together in the retaining configuration and further apart in the open configuration. See first attached diagram.

8. Regarding claim 53, both the first and second parts form an arcuate shape.

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9. Regarding claim 54 & 55, the staple has sharpened end points on the first and second parts.
10. Regarding claim 56, the device is made from wire.
11. Regarding claim 57, the Krumme device is made of a shape memory alloy (abstract.)
12. Regarding claim 59, the fixator contains a plurality of parts that are integral.
13. Regarding claim 60, the device has two first and second parts.
14. Regarding claim 61, the surgical staple of figure 5b meets all the limitations of claims 51, 58, 60, and 61. The Krumme staple contains an equal number of first and second parts, a resilient member (the top section of the staple), and is held together by the attaching structure (the part that bonds each resilient structure together.)
15. Regarding claim 63, the Krumme fixator can hold a graft.
16. Regarding claim 64, the Krumme device illustrated in figure 5a contains two elongated members (one elongated member has been painted gray in the attached diagram, the other one is white.) The elongated members have an open and closed configuration. In the open configuration, the first and second members are spaced; in the closed configuration, the first and second members are closer together.
17. Regarding claim 66, the ends of the first and second parts are sharpened.
18. Regarding claim 67, the elongated members extend entirely between the first and second parts.
19. Regarding claim 68 and 69, the Krumme device discloses all the limitations of claims 68 and 69 which were described in the rejections of claims 51, 53-61, 63-64, and 66-67.

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20. Regarding claim 70, the Krumme device can be normally biased in either configuration, open or closed, depending on the temperature in which it is stored.

21. Claims 51, 52, 64, and 65 are rejected under 35 U.S.C. 102(b) as being anticipated by Shein, US 3,527,2234. As shown in figure 1, Shein discloses a surgical device containing a plurality of first and second parts connected by a resilient member wherein the first and second parts become close together in the retaining configuration and further apart in the open configuration. Additionally, the Shein device contains two elongated members. The elongated members have an open and closed configuration. In the open configuration, the first and second members are spaced; in the closed configuration, the first and second members are closer together. The Shein device also discloses that the elongated members are aligned in a common axis in the closed position.

Allowable Subject Matter

Claim 62 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The following is a statement of reasons for the indication of allowable subject matter: The prior art does not teach a fixator as claimed in claim 51, contained in a kit wherein said kit contains all of the elements of claim 62.

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Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The following patents use shape memory material to cause a shape change in a tissue anchor. US 6,200,330; 5,586,983; 6,113,611; 5,219,358; 6,447,524.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul A Roberts whose telephone number is (703) 305-7558. The examiner can normally be reached on 7:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Milano can be reached on 703-308-2496. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3590 for regular communications and (703) 305-3590 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

Paul Roberts
February 10, 2003



